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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,177	10/30/2003	Joseph D'Agosto	DAG-202	2254

7590

06/27/2005

Alfred E. Miller  
406 West Putnam Avenue  
Greenwich, CT 06830

EXAMINER
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ALI, SHUMAYA B

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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**Office Action Summary**

Application No.

10/697,177

Applicant(s)

D'AGOSTO, JOSEPH

Examiner

Shumaya B. Ali

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☒ Claim(s) 1, 5, 6 and 9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>detailed action</u> .                  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 101*

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 9 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 9 recites "a hard and a soft palate" which is considered a non-statutory subject matter since the limitation is referring to body parts.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. **Claims 1,6, and 9** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1,6, and 9 recite "substantially perpendicular" render indefinite since it is unclear what the applicant considers to be "substantially perpendicular".
4. **Claim 5** recites the limitation "relatively soft" in line 2. There is insufficient antecedent basis for this limitation in the claim.
5. **Claim 6** recites the limitation "the superior surface" in line 3. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

***Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gardy US Patent 4,676,240 in view of Belfer US Patent 5,921,241***

7. As to claim 1, Gardy discloses a gag-less airway (fig.1 reference object 10, hold tongue forward and increase the breathing passage, col.2 lines 63-65), therefore capable of providing a gag-less airway) device for insertion in the user's mouth comprising a flattened tube (fig.1 reference object 10 seems to depict a flat tube) having an unobstructed airway (col.2 lines 60-64), a top surface (a flattened tube inherently has a top and bottom surface) of said tube corresponding to the configuration of the hard palate of the mouth, a bottom surface (a flattened tube inherently has a top and bottom surface; fig.1 seems to depict that the top surface is adapted to the curvature of the upper jaw 16 inside the mouth where the hard palate is anatomically located, see also col.4 lines 15-19) of said tube having traction means (fig.2 reference object 32,30, col.3 lines 55-58, col.4 lines 17-19) thereon for pulling the user's tongue forward upon insertion of the device in the mouth, however does not disclose a flange at the forward end of said device located substantially perpendicular to said airway. As to claim 1, Belfer teaches an anti-snoring device having an adjustable external oral shield ("flange") that contacts the tissue below the nose and the inferior border of the upper lip such that reduces size

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adjustable external oral shield still functions in preventing the lower jaw from moving inferiorly and posteriorly while the user is in the supine position (col.10 lines 44-50). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the antisnoring device of Gardy in view of Belfer to provide a flange for the purposes of preventing the lower jaw from moving inferiorly and posteriorly while the user is in the supine position.

8. As to claim 2, Gardy discloses a gag-less device as claimed in Claim 1 wherein said traction means are spaced ridges (fig.2 reference object 30 and 32 are considered spaced apart).

9. As to claim 3, Gardy discloses a gag-less airway device as claimed in Claim 1 wherein the length of the device only extends through the anterior two thirds of the oral cavity (col.2 lines 65-66).

10. As to claim 4, Gardy discloses a gag-less airway device as claimed in Claim 1 wherein said device is fabricated of an elastomeric material (col.2 lines 65-67).

11. As to claim 5, Gardy does not disclose a gag-less airway device as claimed in Claim 4 wherein said elastomeric material is a relatively soft silicone. As to claim 5, Belfer teaches an antisnoring device that is fabricated from a thermoplastic material (elastomeric resin), which is moldable in shape to the user's lower jaw and perioral structure (col.10 lines 20-23). Additionally teach the thermoplastic material includes silicones (col.5 lines 36-44). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to construct the antisnoring device of Gardy with thermoplastic silicones so that the material can be softened and molded in hot or boiling water, and will return to a hardened and stable form upon cooling to room temperature as taught by Belfer (col.5 lines 40-45).

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12. As to claim 6, Gardy discloses a gag-less airway device (fig.1 reference object 10, hold tongue forward and increase the breathing passage, col.2 lines 63-65), therefore capable of providing a gag-less airway) for insertion in the user's mouth comprising, a flattened tube (fig.1 reference object 10 seems to depict a flat tube) having an unobstructed airway (col.2 lines 60-64), said tube being of such a length that it will not stimulate the gag reflex (fig.1 seems to depict the top surface terminates near the last molar of a patient; a slight distance beyond the last molar is the landmark of the juncture of hard and soft palate. The device as a whole does not extend beyond the hard palate therefore, capable of preventing "gag reflex" which according to the Webster's Medical dictionary may results in contracting the soft palate) in the user when the device is inserted in the oral cavity, the superior surface (a flattened tube inherently has a superior and an inferior surfaces) of said tube corresponding to the hard palate of the mouth (fig.1 seems to depict the top surface terminates near the last molar of a patient, a slight distance beyond the last molar is the landmark of the juncture of hard and soft palate) an inferior surface (a flattened tube inherently has a superior and an inferior surfaces) of said tube having substantially parallel spaced ridges (fig.2 reference object 30 and 32 are considered substantially parallel spaced apart), which are traction means (fig.2 reference object 32,30, col.3 lines 55-58, col.4 lines 17-19) for pulling the user's tongue forward upon insertion of the device in the mouth, however does not disclose a flange at the forward end of said device located substantially perpendicular to said airway. As to claim 6, Belfer teaches an anti-snoring device having an adjustable external oral shield ("flange") that contacts the tissue below the nose and the inferior border of the upper lip such that reduces size adjustable external oral shield still functions in preventing the lower jaw from moving inferiorly and posteriorly while the user is in the supine position (col.10 lines 44-50). Therefore, it would have been obvious to one of ordinary skills in the

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art at the time the invention was made to modify the antisnoring device of Gardy in view of Belfer to provide a flange for the purposes of preventing the lower jaw from moving inferiorly and posteriorly while the user is in the supine position.

13. As to claim 7, Gardy discloses a gag-less airway device (fig.1 reference object 10, hold tongue forward and increase the breathing passage, col.2 lines 63-65), therefore capable of providing a gag-less airway) as claimed in Claim 6 wherein at least one side of said tube is provided with openings (fig.1 reference objects 36 and 38) for the passage of air there through.

14. As to claim 8, Gardy does not disclose a gag-less airway device as claimed in Claim 6 wherein said flange is provided with spaced openings. As to claim 8, Belfer teaches the oral shield ("flange") as discussed above further includes breathing holes (col.8 lines 31-33). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the antisnoring device of Gardy in view of Belfer to provide the shield with breathing holes acting as an air inlet for the purposes preventing airway obstruction of the user.

15. As to claim 9, Gardy discloses an anti-snoring gag-less device for insertion in the user's mouth having a hard and soft palate comprising a flattened tube (fig.1 reference object 10 seems to depict a flat tube), an unobstructed airway (col.2 lines 60-64), a top surface (a flattened tube inherently has a top and bottom surface) of said tube corresponding substantially to the configuration of the hard palate of the mouth, a bottom surface (a flattened tube inherently has a top and bottom surface; fig.1 seems to depict that the top surface is adapted to the curvature of the upper jaw 16 inside the mouth where the hard palate is anatomically located, see also col.4 lines 15-19) of said tube having traction means (fig.2 reference object 32,30, col.3 lines 55-58, col.4 lines 17-19) for pulling the user's tongue forward

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upon insertion of the device in the mouth and maintaining the tongue in a forward position, and the other end of said tube terminating approximately at the juncture of said hard and soft palate (**fig.1 seems to depict the top surface terminates near the last molar of a patient; a slight distance beyond the last molar is the landmark of the juncture of hard and soft palate**), however does not disclose a flange on the forward end of said device located substantially perpendicular to said tube. **As to claim 9, Belfer teaches an anti-snoring device having an adjustable external oral shield ("flange") that contacts the tissue below the nose and the inferior border of the upper lip such that reduces size adjustable external oral shield still functions in preventing the lower jaw from moving inferiorly and posteriorly while the user is in the supine position (col.10 lines 44-50). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the antisnoring device of Gardy in view of Belfer to provide a flange for the purposes of preventing the lower jaw from moving inferiorly and posteriorly while the user is in the supine position.**

16. **As to claim 10, Gardy does not disclose a gag-less airway as claimed in Claim 2 wherein said spaced ridges are saw-like notches, however the applicant has not established criticalities regarding "saw-like notches", therefore, restraining ridges as disclosed by Gardy would be considered to meet the limitation. Additionally, Gardy's ridges (fig.2 reference object 30 and 32) are pertinent to solve the problem addressed by the applicant, which is to maintain the tongue in a forward position (col.3 lines 55-56).**



***Drawings***

17. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, **“a top surface”, “bottom surface”, and “an unobstructed airway”** must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

18. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Specification***

19. The disclosure is objected to because of the following informalities: disclosure lacks-

- Detailed description of figures 3 and 4.
- Positive recitation of “an unobstructed airway” recited in claim 1. Applicant may be refereeing to a channel 14 of figure 1 by the limitation.

Appropriate correction is required.

### ***Claim Objections***

20. Claims 1,5,6, and 9 are objected to because of the following informalities-

- **Claims 1,6, and 9** are objected to as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1,6, and 9 recite "substantially perpendicular" render indefinite since it is unclear what the applicant considers to be "substantially perpendicular".
- **Claim 5** recites the limitation "relatively soft" in line 2. There is insufficient antecedent basis for this limitation in the claim.
- **Claim 6** recites the limitation "the superior surface" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Appropriate correction is required.

### ***Conclusion***


21. The prior art made of record on form PTO-892 and not relied upon disclose anti-snoring device.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Shumaya B. Ali** whose telephone number is **571-272-6088**. The examiner can normally be reached on M-F 8:30 am-4: 30 pm.

23. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Henry Bennett** can be reached on **571-272-4791**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-6088.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Shumaya B. Ali  
Examiner  
Art Unit 3743  
6/22/05

  
Henry Bennett  
Supervisory Patent Examiner  
Group 3700